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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,800	11/06/2000	Thomas Strungmann	4271-29PUS	5697

7590 04/20/2004

Thomas C Pontani
Cohen Pontani Lieberman & Pavane
Suite 1210
551 Fifth Avenue
New York, NY 10176

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,800	STRUNGMANN, THOMAS	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination and Amendment filed 01/02/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/02/04 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frangin et al. US 5,985,915, in view of Poss US 5,616,591.

Frangin teaches a patch for transdermal composition comprising active ingredients, excipient (column 6, lines 24-65), and at least one additional cardioactive agent selected from the group consisting of diuretic, and angiotensin II, e.g.,

candesartan (column 8, lines 43-67). Frangin further teach a transdermal patch composition comprising angiotensin inhibitor agent, e.g., candesartan (column 8, lines 66-67).

Regarding to claims 33 and 38 the reference differs from the claimed invention by not teaching the specific form of candesartan or its' salts. However, it would have been prima facie obvious for one of the ordinary skill in this art to, by routine experimentation determine a suitable form of candesartan suitable for transdermal patch.

The examiner notes that Frangin is silent as to the teaching of diuretic or calcium blocker as a second therapeutic agent. However, Frangin teaches the active ingredients selected from benzofuran can be formulated in combination with one or more pharmaceutically vehicles (see abstract). Thus, it would have been obvious for one of the ordinary skill in this art to select more than one cardioactive agent, e.g. diuretic and angiotensin inhibitor, to obtain a transdermal patch containing candesartan.

Frangin does not teach the claimed transdermal patch.

Poss teaches a composition for transdermal patch comprising an angiotensin inhibitor agent in combination with a diuretic agent as a second compound (columns 7, lines 40 through column 8, lines 1-29). Poss does not suggest the use of a specific compound of angiotensin inhibitor. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify the composition of Frangin using the transdermal patch in view of the teaching of Poss with the expectation of providing a transdermal patch containing candesartan useful for the treatment of heart diseases.

Claims 32-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss and Frangin et al., in view of Jalonen et al. US 5,464,628.

Poss and Frangin are relied upon for the reasons stated above. The references are silent as to the teaching of the ingredients of a transdermal patch.

Jalonen teaches a pharmaceutical composition containing substituted imidazole to be administered transdermally (abstract). The transdermal patch comprises a an impermeable backing layer and an adhesive layer; or an impermeable backing layer, an adhesive layer, and a matrix layer; or a drug reservoir system (column 2, lines 36-64). The backing layer can be flexible or non-flexible materials: polyethylene, or polypropylene; the adhesive layer can be polysiloxanes, polyacrylates, or ethylene-vinyl acetate; and the matrix layer can be of natural or synthetic rubbers (column 3, lines 21-51). The composition further comprising carrier and penetration enhancers, e.g., polyethylene glycol, propylene glycol, isopropanol, ethanol, oil, or a mixture thereof (column 2, lines 65 through column 3, lines 1-20). Thus, it would have been prima facie obvious for one of the ordinary skill in this art to prepare the composition of Poss and Frangin in a transdermal patch in view of the teaching of Jalonen. The reason for this modification is to obtain a candesartan transdermal patch that will provide a high bioavailability of drug penetration.

Response to Arguments

Applicant's arguments filed 01/02/04 have been fully considered but they are not persuasive.

Applicant argues that Frangin does not provide enabling disclosure to teach administration of even the principal active agent (benzofuran derivative) via a transdermal "patch" delivery system in that it does not provide enabling disclosure as to the type and construction of such a patch that could be utilized for the delivery of the benzofuran derivative. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Frangin teaches his compositions can be administered through oral, sublingual, nasal, inhaled, parenteral, topical, rectal, and transdermal, wherein, a transdermal patch is even mentioned (column 6, lines 25-36). The active ingredients to be incorporated into Frangin's compositions including candesartan in combination with benzofuran derivatives (column 8, lines 34-67). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation optimize Frangin's compositions in view of the teaching of Poss.

Applicant argues that not all therapeutically active substances are suitable for transdermal administration (cited Jalonen, column 2, lines 13-29), and therefore, any broad conclusion of obviousness is not warranted and the art specifically teaches away from such a broad conclusion. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the

test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Jalonen teaches a transdermal patch comprising active drugs, including, antihypertensive active agent for the treatment of hypertension (column 1, lines 41-50). Candesartan is a well known for the treatment of heart disease, and hypertension. Therefore, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to combine the teaching of Frangin and Jalonen since the references are teaching transdermal patch containing therapeutic agents, including antihypertensive agent.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nisato is cited as of interest for the teaching of transdermal composition comprising angiotensin II antagonist compound.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600